



News and information for participants in the *VIT*amin D and *Om*ega-3 *Tri*aL (VITAL)

## Update on VITAL Study Timeline

We are approaching the final stretch of pill-taking in VITAL. Although we will continue to send annual study questionnaires for two years beyond this date, ***pill-taking will end on December 31, 2017***. On this date, VITAL participants will have taken their study pills for an average of 5 years, which is the time necessary for VITAL to test whether vitamin D or omega-3 fatty acid (fish oil) supplements can prevent cancer, heart disease, or stroke. Thank you for your partnership as we approach this

milestone—and get closer to answering these important questions. Here's what to expect next:

- Normal follow-up procedures will be in place until December 31, 2017. We will continue to mail you annual follow-up questionnaires to update your health information. Toward the end of this year and into next, we will also mail you enough calendar packs to last until the end of December 2017.
- When pill-taking ends on December 31, 2017, we will mail

you a short questionnaire to collect basic information on new medical diagnoses and your compliance in taking the study capsules.

- Soon after you return this questionnaire to us, we will send you a letter notifying you whether your study capsules contained active vitamin D, active omega-3 fatty acids (fish oil), or placebo.
- We will analyze the data, prepare a manuscript describing the main results of the study, and submit it for publication in a major medical journal. When the manuscript is accepted and published, we will send you a letter or newsletter with a summary of the main findings.
- In addition to the aforementioned short questionnaire to be sent

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### Pill-taking Timeline



### From the VITAL Study Directors

#### Dear VITAL participant,

As VITAL approaches its final year of pill-taking, we would like to offer heartfelt thanks for your enormous contribution to health research. Thanks to your continuing collaboration, VITAL is well on its way to answering the question of whether vitamin D and omega-3 fatty acids (fish oil) can prevent cancer, heart disease, stroke, and other health conditions.

We would also like to stress the importance of taking your

study pills regularly until pill taking ends on December 31, 2017 (see *story above*). We recognize that a few participants who enrolled early will hit their own personal 5-year pill-taking milestone before the official pill-taking stop date. Enrollment in VITAL took place on a rolling basis, with some people joining the study earlier in the recruitment period and others joining later. The earliest enrollers started taking their study pills in the summer of 2011,

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# VITAL on the Go



Karen B., of Connecticut, and her husband Stanley, at an elephant reserve near Victoria Falls, Zimbabwe. The elephant's name is Tusker.

Alwell N., of New York, at the Australian Federal Parliament Building, Canberra, Australia.



Roselyn E., of New Mexico, at the Sea of Galilee, Israel, 2015.

Sisters Mary W. and Michelle M., both of Michigan, at Mackinac Island in Michigan. They write, "We're taking these pills every day. We keep them with our daily medications."



Joe K., PhD, of Oregon, writes, "I am standing in front of a 100-year-old Navajo hogan we are working to restore. It is on the Navajo reservation in New Mexico and belongs to my wife's family."



Jim J., of California, on a bareboat sailing trip in Croatia, Summer 2015.



Penny A., of Massachusetts, at Drake Bay, Osa Peninsula, Costa Rica, February 2016.

Kristina B., of Wisconsin, at the Via Dolorosa, Jerusalem, Israel, February 2015.



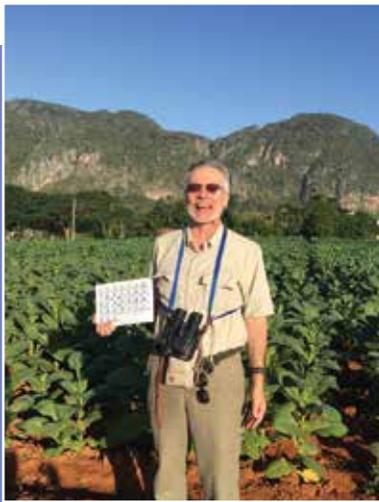
Elaine D., of Maryland, in front of her glass igloo in Kakslauttanen, Finland, November 2015.



Francis G., of Rhode Island, writes, "My capsules have joined me in travels all over the world. Here they are basking in the sun (ever so briefly) on Koh Phayam in the Andaman Sea off the western coast of Thailand. I consider my participating in the VITAL Study as a small contribution to the better understanding of heart health."



Kay K., of Idaho, writes, “After years of reading about the famous Milford Track, in December of 2015 I found myself there. So, at 74 years of age, I ... rinse[d] my shoes in the disinfectant when I got off the boat at the trailhead, and did an 11 km hike. (New Zealand is rabid about keeping areas free of foreign ‘anything’ so shoes are rinsed!). Gorgeous day, beautiful country, lifelong dream realized.”



Paul H., of Mississippi, in Viñales, Cuba.



Sandra O., of Iowa, at the Grand Canyon, Arizona, 2014.

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while the latest enrollers started their pills in the fall of 2013. This means that when pill-taking ends on December 31, 2017, some participants will have taken the study pills for about 6 years while others will have taken them for only 4 years—but the *average* length of time that participants will have taken the pills will be 5 years. An average of 5 years of pill-taking is the amount of time required for VITAL to achieve its goal of determining whether vitamin D and omega-3 supplements have a significant effect on risk for cancer, heart disease, and stroke. This is why we are asking that all participants—

even the early enrollers—continue their pills until December 31, 2017 if at all possible. Please help ensure the success of VITAL by continuing to take the study pills as VITAL enters its final pill-taking stretch. We know that taking the study pills day in and day out is not an easy task, and we are extremely grateful for each day, week, month, and year that you are able to do so. Of course, if you choose to stop the study pills prior to the official pill-taking end date, please just let us know. And, as always, if you have questions or comments about any aspect of the study, please feel free to contact us at 1-800-388-3963, vitalstudy@partners.org, or the postal address at the right. Thank you!

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at the end of pill-taking, we will send you two more of your usual yearly questionnaires—one in 2018 and one in 2019—to collect supplemental study data, including updated information on known and potential risk factors for cancer and cardiovascular disease, use of medications, and medical history. These data will not only be important in helping to answer the main research questions around which VITAL was designed but will also allow us to examine new hypotheses regarding health promotion and disease prevention.

VITAL is one of only two large (10,000 participants or more) randomized clinical trials of vitamin D for the prevention of cancer, heart disease, and stroke—and the only such trial in a racially and ethnically diverse study population—in the world. It is also the only large trial of fish oil supplements in a generally healthy population. Many patients, healthcare providers, and professional medical organizations are eagerly awaiting the trial’s results. Please help VITAL achieve its goals by continuing to take your study pills through December 31, 2017 and by completing the study questionnaires both before and after pill-taking ends.



**VITamin D and  
Omega-3 Trial  
(VITAL Study)**

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# VITAL Q&A

**Q. Why do many clinical trials take several years to get answers to research questions?**

**A.** VITAL and many other clinical trials that you may have read about are *primary prevention trials* in initially healthy people, as opposed to a *treatment trial* in those who are already ill. Testing interventions for the primary prevention of chronic diseases such as cancer or cardiovascular disease requires that a large group of participants at usual risk for developing these diseases be followed for a sufficient period of time to allow the agents under study—in this case, vitamin D and omega-3 fatty acid supplements—to exert their biological effects. Thanks to the willingness and enthusiasm of our participants, who will take the study capsules for an average of 5 years, VITAL is expected to produce results that will help resolve continuing uncertainties and shape national guidelines about who should (or should not) take vitamin D and fish oil supplements to prevent cancer, heart disease, stroke, and other health problems.

**Q. Recent news stories have reported on problems with quality control in the dietary supplement industry. What can you tell me about the quality of the VITAL study capsules?**

**A.** Thank you for raising this important question. The concerns raised by these reports do NOT

apply to VITAL. Please be assured that the specific vitamin D and fish oil supplements (and placebos) used in VITAL have undergone extensive quality-control testing to verify and ensure that they contain the correct nutrients in the correct doses, are free from contaminants, arrive fresh at your doorstep, and remain shelf stable for at least 1½ years from the time you receive them.

Prior to starting the study, we worked intensively with the supplement manufacturers, packaging suppliers, and quality testers to address these critically important issues. The results of these tests were carefully reviewed and approved by the U.S. Food and Drug Administration (FDA) before we began the study. VITAL's vitamin D supplement is made by the California-based company Pharmavite (and sold commercially under the Nature Made label). VITAL's fish oil supplement (Omacor® fish oil, 1 gram) is made by the Norway-based company Pronova (recently acquired by BASF) and is a formulation available only by prescription. One problem with many over-the-counter fish oil supplements is that they can spoil or become rancid. In our stability tests, the packaged study capsules were subjected to extreme climate conditions such as temperatures above 100 degrees Fahrenheit and high humidity. The results of these tests demonstrated that the capsules and nutrient content remain stable. Please store

the capsules in the calendar packs (keep unopened packs inside of the aluminum pouches – the way they're shipped to participants) to avoid any potential problems.

**Q. Why do you ask for the name and telephone number of a contact person?**

**A.** In a long-term study such as VITAL, we occasionally lose touch with study participants when they move or have other changes in their status. We will write or telephone your contact person to ask for your current address or phone number only if we cannot reach you after multiple attempts.

**Q. Why do you ask for consent to obtain and review medical records for certain conditions reported on the questionnaires?**

**A.** The main reason for reviewing records is to categorize the medical reports from participants using a uniform set of diagnostic standards. By looking at actual medical records, we can, for example, use the same criteria in reviewing cardiograms to decide whether to classify reports as specific types of heart attacks. Your cooperation in providing this consent is greatly appreciated. Please be assured that any information that we receive is kept strictly confidential and is used only for the aforementioned purpose.